Subject: Fwd: Lucentis media inquiry
From: Jill Castellano <jillcastellano@inewsource.org>
Date: 4/23/19, 2:39 PM
To: Brad Racino <bradracino@inewsource.org>

---------- Forwarded message ---------
From: **Andrew Villani** <villani.andrew@gene.com>
Date: Tue, Apr 23, 2019 at 2:38 PM
Subject: Lucentis media inquiry
To: <jillcastellano@inewsource.org>

Jill,

Thank you for reaching out. Please see below for our response to your questions.

-Andrew

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We do not comment on third party investigations. However, Genentech holds all investigator-sponsored trials to the same high standards to which we hold ourselves. As such, sponsors are required to fulfill all regulatory requirements and comply with all relevant laws.

As noted in the full prescribing information, new-onset or worsening of existing cataracts have been observed in some patients during pivotal clinical trials of ranibizumab in wet AMD. At 12 months, 17 percent of ranibizumab-treated wet AMD patients enrolled in our clinical trial experienced cataract versus 14 percent of patients in the control group. At 24 months, 11 percent of ranibizumab-treated wet AMD patients enrolled in our clinical trial experienced cataract versus 9 percent of patients in the control group. This information can also be found in our label in Table 1. You can find that here: https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125156s105lbl.pdf.

It's also important to note that cataracts are more common in the elderly and also in patients with diabetes. Looking at Table 1 of our label, while the cataract rates are similar between the ranibizumab and the control groups for each trial, there are differences from one disease to other. For example, rates are highest in diabetic macular adema and diabetic retinopathy where you have two risk factors: diabetes and relatively advanced age; the next highest rates are in age-related macular degeneration (AMD) which is the oldest population and the lowest rates are in retinal vein occlusion (RVO) where patients tend to be younger. These data suggest that cataract rates may be driven by baseline risk factors such as age and the underlying disease, not ranibizumab treatment. Of note,

cataracts were not highlighted as a concern in a recent assessment of the efficacy and safety of anti-VEGF therapies for wet AMD by the American Academy of Ophthalmology (attached).

For your information, serious adverse reactions related to the injection procedure have occurred in <0.1% of intravitreal injections, including endophthalmitis, rhegmatogenous retinal detachment, and iatrogenic traumatic cataract.

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Andrew Villani
Associate Director, Corporate Relations
Genentech, a member of the Roche Group
O: 650-467-2152
C: 650-825-0704
villani.andrew@gene.com

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Jill Castellano
Investigative Data Reporter, *inewsource*
Email: jillcastellano@inewsource.org
Phone: (914) 629-1750
Twitter: @jill_castellano
PGP: Public Key

Attachments:

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